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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/913,325	08/10/2001	Martin Gleave	UBC.P-020	8469
21121	7590	07/28/2005	EXAMINER	
OPPEDAHL AND LARSON LLP			VIVLEMORE, TRACY ANN	
P O BOX 5068			ART UNIT	PAPER NUMBER
DILLON, CO 80435-5068			1635	
DATE MAILED: 07/28/2005				

Please find below and/or attached an Office communication concerning this application or proceeding.

*KC*

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	09/913,325	GLEAVE ET AL.	
	Examiner Tracy Vivlemore	<b>Art Unit</b> 1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 29 April 2005.
- 2a) This action is FINAL.                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-34 is/are pending in the application.  
     4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 1-4,6-9,12-15,18-27,29 and 30 is/are rejected.
- 7) Claim(s) 5,10,11,16,17,28 and 31-34 is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
     a) All    b) Some \* c) None of:  
         1. Certified copies of the priority documents have been received.  
         2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
         3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____  |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>4/29/05</u> | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
|  | 6) <input type="checkbox"/> Other: _____                                    |



## **DETAILED ACTION**

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Any rejection not reiterated in this Action is withdrawn.

### ***Claim Rejections - 35 USC § 112***

The rejection of record of claims 1, 2, 6-8, 12-25, 30, 32 and 34 under 35 U.S.C. 112, first paragraph for lack of enablement is withdrawn in view of the 132 declaration submitted April 29, 2005.

The rejection of record of claims 1, 2, 7, 8, 12-17, 19-25, 30, 32 and 34 for not meeting the written description requirement of 35 USC 112, first paragraph is withdrawn.

### ***Response to Arguments Claim Rejections - 35 USC § 112***

Claims 6 and 18 are maintained as rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement for the reasons of record.

1. Applicant asserts that because claims 6 and 18 are original claims, applicant has possession of the idea of using any agent that decreases expression of TRPM-2 for the purposes stated in these claims. This argument is not persuasive because neither the existence of a claim as an original claim nor Applicant's belief they were in possession of the idea that any agent that inhibits TRPM-2 expression could perform the claimed

methods are a guarantee that the written description requirement has been fulfilled. Although the claims are not directed to compounds but to methods, the compounds are an important part of the inventions because they are the "active ingredient". The claims encompass the use of inhibitors of TRPM-2 other than antisense oligonucleotides and while knowledge of a gene sequence provides the information needed by the skilled artisan to produce antisense oligonucleotides, the knowledge of a gene sequence does lead the skilled artisan to the structure of inhibitors that are antibodies or small molecules. Applicant states that the Examiner's citation Rochester v. Searle is not directly applicable to the present application because in that case no compounds capable of use in the claimed methods had been disclosed. When considering inhibitors of TRPM-2 that are not antisense oligonucleotides, the instant application parallels the Rochester case because there is no disclosure of compounds that are small molecules or antibodies that capable of use in the claimed methods.

### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA

1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

2. Claims 1, 3, 6-9, 12-15, 18-21, 24, 26, 29 and 30 rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 2-6, 10 and 11 of U.S. Patent No. 6,900,187. Although the conflicting claims are not identical, they are not patentably distinct from each other because the scope of claim 2 of the patent is fully encompassed within claims 1 and 3 of the instant Application, the scope of claim 3 of the patent is fully encompassed within claims 6-9 of the instant Application, the scope of claims 4 and 5 of the patent are fully encompassed within claims 12, 13 and 29 of the instant Application, the scope of claim 6 of the patent is fully encompassed within claims 14, 15, 21 and 30 of the instant Application, the scope of claim 10 of the patent is fully encompassed within claims 18-21 of the instant Application and the scope of claim 11 of the patent is fully encompassed within claims 24 and 26 of the instant Application. Although the modifications recited in the patented

claims are not contemplated in the instant specification, the sequence is identical, thus each of the patented claims is a species that anticipates and is an obvious variation of the generic claims of the instant application.

3. Claims 18-23 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-6 of copending Application No. 09/967,726. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of each application are directed to methods of enhancing the chemo- or radiation sensitivity of a cancer cell using an antisense oligonucleotide directed to TRPM-2. While the claims of the '726 explicitly recite that chemo or radiation therapy is administered before the antisense and the instant claims do not explicitly state when chemo or radiation therapy is administered, even absent an explicit step requiring administration of the additional anti-cancer therapeutic it would be obvious to one of ordinary skill to actually perform the additional anti-cancer treatment stated in the preambles of both independent claims to be the intended purpose of the method.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

#### ***Response to arguments - Double Patenting***

Applicant states the provisional double patenting rejection made in the previous Office Action over the application from which the patented claims have issued used an

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improper standard, stating the now-patented claims are a species of the generic claims of the instant application and that an analysis of whether the claims are an obvious variant of one another must be done. This argument is not persuasive because stating a species claim anticipates a genus claim is a finding that the claims are obvious variants; anticipation is the epitome of obviousness. Additionally, Applicant asserts that because the instant application is the earlier application a two-way test for obviousness must be used. This argument is not persuasive because a one-way test for obviousness is the standard in the absence of evidence that administrative delay by the Office resulted in the later filed application issuing first. An improper extension of patent term is not an issue in this case, but the policy behind a double patenting rejection is also directed to preventing possible harassment by multiple assignees, which would be prevented by the filing of a terminal disclaimer.

***Response to Arguments - Claim Rejections - 35 USC § 102/35 USC § 103***

Claims 1, 2, 4, 24, 25 and 27 are maintained as rejected under 35 U.S.C. 102(b) as being anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Sensibar et al.

4. Applicant states that an inherency argument is more appropriate for composition claims, which are not present in the instant case. This argument is not persuasive because MPEP 2112 makes clear that 102/103 rejections are appropriate for method claims as well as composition claims.

"[w]here applicant claims a composition in terms of a function, property or characteristic and the composition of the prior art is the same as that of the claim but the function is not explicitly disclosed by the reference, the examiner may make a rejection under both 35 USC 102 and 103, expressed as

a 102/103 rejection. ‘There is nothing inconsistent in concurrent rejections for obviousness under 35 USC 103 and for anticipation under 35 USC 102’ *In re Best*, 562 F.2d 1252, 1255 n.4, 195 USPQ 430, 433 n.4 (CCPA 1977). This same rationale should also apply to product, apparatus, and process claims claimed in terms of function, property or characteristic. Therefore, a 35 USC 102/103 rejection is appropriate for these types of claims as well as for composition claims.”

5. Applicant states that Sensibar et al. teach an antisense that reduces expression of TRPM-2 in an LNCaP cell line that has been modified to overexpress TRPM-2. However, the experiments where Sensibar overexpressed TRPM-2 to prevent TNF- $\alpha$  induced apoptosis are a different set of experiments than those describing antisense inhibition of TRPM-2 expression. The paragraphs relating to the antisense experiments do not state these cells had been modified to overexpress TRPM-2. Sensibar et al. disclose that the cells used are androgen sensitive and their experiments perform the step of the claimed method, treating androgen sensitive prostatic tumor cells with an antisense oligonucleotide that inhibits expression of TRPM-2. Absent evidence to the contrary, the experiments described by Sensibar et al. would have the effect of delaying progression of prostatic tumor cells from to an androgen-independent state.

#### ***Claim Rejections - 35 USC § 103***

The rejections of record of claims 12, 13 and 31 as obvious over Sensibar et al. and Benner et al. are withdrawn. Applicant’s arguments presented in application 09/967,726 that Sensibar does not teach that TRPM-2 is involved in cancer cell growth are persuasive. Although TRPM-2 is related to apoptotic cell death, no teaching has been found in the prior art that TRPM-2 is directly involved in cancerous cell growth or proliferation.

***Allowable Subject Matter***

Claims 5, 10, 11, 16, 17, 28 and 31-34 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Tracy Vivlemore whose telephone number is 571-272-2914. The examiner can normally be reached on Mon-Fri 8:45-5:15. If attempts to reach the examiner by telephone are unsuccessful, the examiner's acting supervisor, Andrew Wang can be reached on 571-272-0811.

**On July 15, 2005, the Central FAX Number will change to 571-273-8300.**

**This new number is already operational and faxes sent to the old number (703-872-9306) will be routed to the new number until September 15, 2005.**

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent

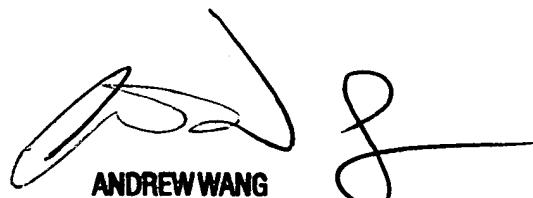
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For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

Tracy Vivlemore  
Examiner  
Art Unit 1635

TV  
July 19, 2005



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